



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,813	03/15/2004	David William Scharp	NOVCEL.028C1	1616
36647	7590	09/06/2006	EXAMINER	
NOVOCELL, INC. 31 TECHNOLOGY DRIVE SUITE 100 IRVINE, CA 92618			HISSONG, BRUCE D	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 09/06/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/800,813

Applicant(s)

SCHARP ET AL.

Examiner

Bruce D. Hissong, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/15/04, 10/7/04, 10/15/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1646

## DETAILED ACTION

### **Formal Matters**

Claims 1-12 are currently pending and are the subject of this office action.

### **Information Disclosure Statement**

1. The information disclosure statements received on 3/15/2004, 10/15/2004, and 11/15/2004 have been fully considered by the Examiner.

2. The information disclosure statement received on 10/7/2004 has been fully considered by the Examiner. Citations 3 and 4 have been lined-through because they reference US Application numbers. The corresponding pre-grant publication numbers have been entered on PTO form 892.

### **Drawings**

The drawings submitted on 3/15/2004 are objected to for having inadequately labeled figures. Specifically, the X-axis label for figure 1 is unreadable. Correction is required.

### **Claim Objections**

The Examiner suggests the syntax of claim 1 can be improved by amending the claim to read "...differentiated non-hormone-producing pancreatic cells....".

### **Claim Rejections - 35 USC § 112, first paragraph - enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1646

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of converting differentiated, non-hormone-producing cells into differentiated hormone-producing cells wherein the hormone is insulin, does not reasonably provide enablement for methods for converting differentiated, non-hormone-producing cells into differentiated cells that produce any other hormone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The breadth of the claims is excessive because, as written, the claim read on a method of converting a differentiated, non-hormone-producing pancreatic cell into a differentiated pancreatic cell that can produce any hormone. Although the specification teaches methods for producing insulin-producing cells, it is not enabling for a method of producing a differentiated pancreatic cell capable of producing any other hormone. There is no guidance or examples in the specification that teach how to convert a differentiated, non-hormone-producing pancreatic cell into a differentiated pancreatic cell that produces any hormone other than insulin. Furthermore, a person of ordinary skill in the art would not be able to predict how to convert a differentiated non-hormone-producing pancreatic cell into a cell that produces any hormone, other than insulin, without further undue experimentation. For example, a skilled artisan would not be able to predict, without further, undue experimentation, how to culture pancreatic cells using the claimed methods in order to produce differentiated pancreatic cells that secrete estrogen or pituitary hormone.

Therefore, the breadth of the claims is excessive because they read on methods of producing differentiated hormone-producing pancreatic cells with no limitations as to the hormone produced by said cells. The specification provides guidance and examples only for the culturing of insulin-producing cells. Therefore, due to the excessive breadth of the claims, the lack of guidance in the specification, and the unpredictability inherent in the instant invention and the art regarding the conversion of a pancreatic cell into a cell that can secrete any

Art Unit: 1646

hormone, a person of ordinary skill in the art would require further, undue experimentation in order to practice the instant invention in a manner commensurate with the full scope of the claims.

**Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 1 and 7 recite numerous compounds represented by undefined acronyms. For example, TGF- $\beta$  SRII, DMF, and DIF-1 are all recited in the claims but are not defined. The claims are indefinite because these acronyms are not defined after their first use in the claims. Claims 2-6 and 8-12 are rejected for depending from rejected claims 1 or 7.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsang *et al* (US 2004/0141957 – cited in the information disclosure statement received on 10/15/2004 as application no. 10/766,099). The claims of the instant invention are drawn to a method of converting differentiated non-hormone producing pancreatic cells into differentiated hormone-producing cells, wherein said method comprises: (a) culturing differentiated non-hormone producing pancreatic cells in a first cell culture medium comprising a basal medium, with or

Art Unit: 1646

without serum, with or without growth factors, and (b) culturing the resulting stem cells in a second culture system with a second culture medium comprising at least one compound from Group A and at least one compound from Group B. The claims are further drawn to a method of culturing stem cells into differentiated hormone-producing cells, comprising culturing the stem cells in a cell culture system with basal medium without serum and at least one compound from Group A and one compound from Group B.

Tsang *et al* discloses methods for culturing pancreatic stem cells having an intermediate stage of development, wherein said intermediate-stage pancreatic stem cells can be cultured to produce insulin-producing cells (see abstract; paragraphs 0016-0017, 0029). Specifically, Tsang *et al* disclose methods of culturing isolated, differentiated pancreatic cells, which can include whole pancreas cell suspensions, or fractions containing differentiated acinar cells (paragraph 0057-0064). Tsang *et al* teaches that different types of basal media can be used, including RPMI-1640, DMEM, and F12 media (paragraph 0074), as well as media formulations with and without serum (paragraph 0030). Tsang *et al* further teaches that the development of the intermediate-stage pancreatic stem cells is enhanced by serum-containing media, whereas generation of insulin-producing cells from the intermediate-stage stem cells is favorable using media with low serum levels, or no serum (paragraph 0030, 0075-0087). Finally, Tsang *et al* discloses culturing cells with various additives, including laminin (paragraph 0071), which is listed in the compounds of Group A, and insulin (paragraph 0094), which is listed in the compounds of Group B.

Therefore, by teaching methods for differentiating and/or culturing differentiated pancreatic cells into pancreatic stem cells, and also differentiating the stem cells into insulin-producing cells culture methods including media formulations with and without serum, and media formulations containing at least one compound from Group A (laminin) and at least one compound from Group B (insulin), Tsang *et al* meets the limitations of claims 1 and 7 of the instant invention.

2. Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonner-Weir (US 6,815,203 – cited in the information disclosure statement received on 11/15/2004). The subject matter of claims 1 and 7 of the instant invention is discussed *supra*.

Bonner-Weir *et al* disclose methods for “dedifferentiation” of pancreatic cells, which can then “redifferentiate” into insulin-producing islet cells (column 1, lines 44-60). Specifically, the

Art Unit: 1646

methods of Bonner-Weir involve isolation of pancreatic cells, including differentiated exocrine pancreatic cells (i.e. acinar cells), and culturing them in conditions that promote "dedifferentiation" into an intermediate pancreatic stem cell type that is capable of subsequent differentiation into an insulin-producing cell. The methods of "dedifferentiation" are disclosed at column 1, line 61 – column 4, line 8; column 10, line 50 – column 12, line 23; and column 27, lines 30-51). Bonner-Weir *et al* teaches the use of various media, including CMRL, DMEM, and/or F12 media, which can be with or without serum (column 10, lines 62 – 66; column 11, line 65 – column 12, line 13), and can contain various additives or supplements, including insulin, transferrin, or selenium (column 12, lines 7-13).

Methods for producing insulin-producing islet cells from the "dedifferentiated" pancreatic stem cells is disclosed at column 4, line 9 – column 6, line 12; column 12, line 24 – column 13, line 6; column 27, line 51 – column 28, line 9). Bonner-Weir *et al* discloses the use of various media, including DMEM and/or F12 without serum, and including additives or supplements such as laminin (column 12, lines 26-32), which is a compound from Group A, and insulin (column 6, lines 15-20; column 27, lines 51-57), which is a compound from Group B. These culture conditions were shown to induce the proliferation to the dedifferentiated pancreatic stem cells into insulin-producing islet cells (column 30, lines 64-65; column 31, lines 30-39).

Therefore, Bonner-Weir *et al* disclose methods for producing intermediate-type pancreatic stem cells, which can be further differentiated into insulin-producing cells, wherein said methods are commensurate in scope with the claims of the instant invention regarding use of basal media, with and without serum, and at least one compound (laminin) from Group A and at least one compound (insulin) from Group B. For these reasons, the disclosure of Bonner-Weir *et al* anticipates claims 1 and 7 of the instant application.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1646

1. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsang *et al* in view of Follettie *et al* (US 5,935,852 – cited in the information disclosure statement received on 10/15/2004). The subject matter of independent claims 1 and 7 is discussed *supra*. The claims are further drawn to the methods of claims 1 or 7, wherein the culture conditions comprise addition of at least two, three, four, or five compounds from Group A, and at least two, three, four, or five compounds from Group B.

The disclosure of Tsang *et al* is discussed *supra*. In addition to teaching culture conditions using laminin (Groups A and B) and insulin (Group B) as growth factors/additives, Tsang *et al* further teach the use of other culture growth factors/additives, including epidermal growth factor (EGF), growth hormone, progesterone, selenium, and transferrin. Thus, including insulin, Tsang *et al* teaches culturing pancreatic cells with at least 5 members of Group B. However, with the exception of insulin, Tsang *et al* does not teach culturing pancreatic cells with any member of Group A.

Follettie *et al* teaches the use of cerebrus family members and additional growth factors/additives in methods of culturing various cell types, including pancreatic cells. Included as growth factors/additives that can be used to culture types such as pancreatic cells are activin, bone-morphogenic proteins (BMP), transforming growth factor (TGF)- $\beta$ , and sonic hedgehog.

It would have been obvious to one of ordinary skill in the art, at the time the instant invention was conceived, to combine the teachings of Tsang *et al* with those of Follettie *et al* to practice the instant invention. The motivation to do so comes from Tsang *et al*, which as discussed *supra*, teaches methods of culturing differentiated, non-hormone producing pancreatic cells into non-hormone producing pancreatic stem cells, and then further differentiating the pancreatic stem cells into insulin-producing cells. Tsang *et al* teaches the culture conditions, including basal media with and without serum where appropriate, and various additives, including 1 compound from Group A (laminin) and at least five compounds from Group B (laminin, insulin, transferrin, selenium, EGF, and progesterone). Further motivation to use compounds from Group A comes from Follettie *et al*, which teaches that compositions comprising activin, BMP, TGF- $\beta$ , and sonic hedgehog are useful for culturing pancreatic cells. Thus, the combined teachings of Tsang *et al* and Follettie *et al* teach the use of at least five compounds from Group A (laminin, activin, BMP-2, TGF- $\beta$ , sonic hedgehog, and cholera toxin). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the



Art Unit: 1646

invention was made, to practice methods of culturing pancreatic cells with media containing the growth factors/additives of Tsang *et al* and Follettie *et al*, because the molecules are taught individually to be effective for supporting the growth and/or differentiation of pancreatic cells. *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

In summary, because the combined teachings of Tsang *et al* and Follettie *et al*, teach methods and compositions for culturing and/or differentiation of pancreatic cells into insulin-producing cells, a person of ordinary skill in the art would have both the motivation, and a reasonable expectation of success, in practicing the methods set forth in the claims of the instant invention.

2. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsang *et al* in view of Follettie *et al* (US 5,935,852 – cited in the information disclosure statement received on 10/15/2004), and further in view of Holz *et al* (*Biochimie*, 2000, Vol. 82, p. 915-926). The subject matter of independent claims 1 and 7 is discussed *supra*. Claims 6 and 12 are further drawn to the methods of claims 1 or 7, wherein the culture conditions comprise addition of at least six compounds from Group A, and at least six compounds from Group B.

The disclosures of Tsang *et al* and Follettie *et al* are discussed *supra*. Holz *et al* teaches that cholera toxin is a strong stimulator of insulin production by pancreatic cells (abstract; p. 916-917).

It would have been obvious to one of ordinary skill in the art, at the time the instant invention was conceived, to combine the teachings of Tsang *et al* with those of Follettie *et al* and Holz *et al* to practice the instant invention. The motivation to do so comes from Tsang *et al*, which as discussed *supra*, teaches methods of culturing differentiated, non-hormone producing pancreatic cells into non-hormone producing pancreatic stem cells, and then further differentiating the pancreatic stem cells into insulin-producing cells. Tsang *et al* teaches the culture conditions, including basal media with and without serum where appropriate, and various additives, including 1 compound from Group A (laminin) and 6 compounds from Group B (laminin, insulin, transferrin, selenium, EGF, and progesterone). Further motivation to use compounds from Group A comes from Follettie *et al*, which teaches that compositions

Art Unit: 1646

comprising activin, BMP, TGF- $\beta$ , and sonic hedgehog are useful for culturing pancreatic cells. Additionally, Holz *et al*, by teaching that cholera toxin stimulates insulin secretion from pancreatic cells, provides the motivation for culturing pancreatic cells with insulin in order to produce insulin-producing cells. Thus, the combined teachings of Tsang *et al*, Follettie *et al*, and Holz *et al* also teach the use of at least six compounds from Group A (laminin, activin, BMP-2, TGF- $\beta$ , sonic hedgehog, and cholera toxin). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made, to practice methods of culturing pancreatic cells with media containing the growth factors/additives of Tsang *et al*, Follettie *et al*, and Holz *et al* because the molecules are taught individually to be effective for supporting the growth and/or differentiation of pancreatic cells. *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

In summary, because the combined teachings of Tsang *et al*, Follettie *et al*, and Holz *et al* teach methods and compositions for culturing and/or differentiation of pancreatic cells into insulin-producing cells, a person of ordinary skill in the art would have both the motivation, and a reasonable expectation of success, in practicing the methods set forth in the claims of the instant invention.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with

Art Unit: 1646

this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-30, 32-45, and 47-57 of copending Application No. 10/447,325. Although the conflicting claims are not identical, they are not patentably distinct from each other. The subject matter of the instant application is discussed supra. The '325 application also recites methods of culturing differentiated non-insulin-producing pancreatic cells under conditions which produce non-insulin-producing pancreatic stem cells. The culture methods involve a basal medium, with and without serum, and various growth factors/additives, including one member from Group A of the instant application (laminin), and several members from Group B (for example, insulin, transferrin, selenium). Also claimed is a method for culturing the non-insulin-producing pancreatic stem cells under conditions that result in production of insulin-producing pancreatic cells. The culture methods involve a basal medium, without serum, and with various growth factors/additives, including one member from Group B of the instant application (laminin), and several members from Group B (insulin, transferrin, selenium).

Therefore, both the instant application and the '325 application claim methods of culturing pancreatic cells to produce non-insulin producing stem cells, and then subsequently produce insulin-producing pancreatic cells. Furthermore, the methods from both co-pending applications claim the use of a basal medium, with and without serum, and additives/growth factors such as laminin and insulin/transferrin/selenium. Thus, it would be obvious to one of ordinary skill in the art to practice the methods of claims 1 and 7 of the instant invention by following the methods set forth in the claims of the '325 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28, 39-48, and 55-63 of copending Application No. 10/515,421. Although the conflicting claims are not identical, they are not patentably distinct from each. The subject matter of the instant application is discussed supra.

Art Unit: 1646

The '421 application also recites methods of culturing differentiated non-insulin-producing pancreatic cells under conditions which produce non-insulin-producing pancreatic stem cells, and then culturing the non-insulin producing stem cells under conditions which result in the production of insulin-producing pancreatic cells. The culture methods involve a basal medium, with and without serum, and various growth factors/additives, including six members from Group A of the instant application (laminin, betacellulin, cholera toxin, met-enkephalin, activin A, and sonic hedgehog), and six members from Group B (activin A, laminin, insulin, selenium, transferrin, and EGF). Therefore, both the instant application and the '421 application claim methods of culturing pancreatic cells to produce non-insulin producing stem cells, and then subsequently produce insulin-producing pancreatic cells. Furthermore, the methods from both co-pending applications claim the use of a basal medium, with and without serum, and additives/growth factors, including at least 6 members from Group A of the instant application and at least 6 members from Group B. Thus, it would be obvious to one of ordinary skill in the art to practice the methods of claims 1-12 of the instant invention by following the methods set forth in the claims of the '421 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH  
Art Unit 1646



**ROBERT S. LANDSMAN, PH.D.**  
**PRIMARY EXAMINER**